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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 12/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/979,509	Applicant(s) KAWASAKI ET AL.	
	Examiner Phyllis G. Spivack	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 16 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-18 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-6, 10-18 and 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____ |

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A Preliminary Amendment filed November 23, 2001 is acknowledged wherein claims 19-30 are canceled and new claims 34-36 are presented. Accordingly, claims 1-18 and 31-36 are pending.

Applicants' Response to the Restriction Requirement, filed October 16, 2003, is acknowledged. Applicants have elected with traverse Group I, drawn to compositions comprising a MAG expression promoter, and methods for prophylaxis and/or therapy thereof.

Applicants argue the traversal is based on the fact that claims 7-9 are directed to a method of use for the compounds of the elected claims.

The specification on page 16, lines 18-21, refers to "*in vitro* or *in vivo* expression of MAG at a gene level or a protein level". Such subject matter is properly encompassed in molecular biology, Class 435, not pharmaceutical compositions. The restriction requirement as set forth is still deemed proper, is adhered to and is hereby made FINAL.

Accordingly, the subject matter presently under consideration are those methods for prophylaxis and/or therapy of a disease and compositions thereof, claims 1-6, 10-18 and 31-36. The Examiner regrets the inadvertent omission in the Restriction Requirement of claims 34-36 that were presented in a Preliminary Amendment filed November 23, 2001. Claims 7-9 are withdrawn from consideration by the Examiner, 37 C FR 1.142(b), as being directed to non-elected subject matter. Re-affirmation of the elected Group is requested when Applicants respond to this Office Action.

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An Information Disclosure Statement filed February 25, 2002 is further acknowledged and has been reviewed.

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: on page 3 of the specification, the paragraph beginning with "As" and each claim ending with the recitation "of human". A review of the entire specification is strongly urged.

The disclosure is objected to for the following informality: The referenced term "Y-128" could not be located in the REGISTRY file. On page 16, line 5, of the specification "(Y-128 to be mentioned later)" is noted. A clear definition of Y-128 is not seen. Is the compound Y-20811, benzoic acid, 4-[hydroxy[5-(1H-imidazol-1-yl)-2-methylphenyl]methyl]-3,5-dimethyl intended?

Appropriate correction is required.

Claims 2-4 are objected to under 37 C FR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants are required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. Intended use confers no patentable weight to composition claims. In re Hack, 114 USPQ 161.

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Claims 2-4, 10-18 and 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The recitations “inclusive of human” and “mainly represents” render the claims in which they appear vague and indefinite. It is unclear whether or not claim limitations are intended.

Claims 10-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to the prophylaxis and/or treatment of any disease caused by hypomyelination, dysmyelination, demyelination or, specifically, multiple sclerosis, encephalitis, myelitis, Guillain-Barre syndrome, chronic inflammatory demyelinating polyradiculitis, heavy metal toxicosis, diphtheria toxicosis, hypothyroidism, metachromatic leukodegeneration or Charcot-Marie-Tooth disease. The specification provides support for the administration of a single compound termed “Y-128” as demonstrating a positive effect on myelination of axon.

Attention is directed to In re Wands, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

- 1) the quantity of experimentation necessary

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- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to prevention and/or treatment of any disease which is caused by hypomyelination, dysmyelination, demyelination or, specifically, those pathologies recited in claims 4, 16 and 18.

The relative skill of those in the art is generally that of a Ph.D or M.D.

Each particular myelin-related disease has its own specific characteristics and etiology. The broad recitations “prophylaxis and/or therapy of a disease caused by hypomyelination” and “prophylaxis and/or therapy of a disease mainly presenting dysmyelination or demyelination” are

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inclusive of many conditions that presently have no established successful therapies or approaches to prophylaxis.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are very broad and inclusive of any disease caused by hypomyelination, dysmyelination, demyelination or specific pathologies, as recited in claims 4, 16 and 18.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the administration of a single agent referenced as "Y-128". Support is provided solely through Figure 3 wherein the compound demonstrates a positive effect on myelination of axon.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which particular compound, other than Y-128, would be preferred for treatment or prophylaxis of each individual disorder among the many alleged diseases characterized by myelin-associated glycoprotein dysfunction. The skilled artisan would expect the interaction of a particular drug in the prophylaxis and/or treatment of a particular disease state to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for each agent. The instant specification sets forth no such understanding nor any criteria for extrapolating beyond the single agent "Y-128". Even for the one compound set forth, no clear direction is provided to treat specific disease states. Absent

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reasonable *a priori* expectations of success for using a particular chemotherapeutic agent to treat any particular myelin-associated disease, one skilled in the medical arts would have to test extensively many compounds to discover which particular pathology responds to that particular compound. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 31, 32 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi et al., EP 0 881 218.

Hayashi teaches preventives/ remedies, pharmaceutical compositions and commercial packages comprising 4-[α -hydroxy-2-methyl-5-(1-imidazolyl)benzyl]-3,5-dimethylbenzoic acid. See page 4, lines 28-30. The claims differ in that the present claims do not allow a hydroxy group for R¹, rather an alkoxy group. However, one skilled in the art in view of Hayashi's teaching would have been motivated to prepare pharmaceutical compositions and commercial formulations wherein a methoxy group is utilized in place of hydroxy. Such would have been obvious in the

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absence of evidence to the contrary because the two compounds are homologues. It would have been reasonable to expect compounds of such close structural similarity would each be effective in the prophylaxis and/or therapy of diabetes. Intended use confers no patentable weight to composition claims. In re Hack, 114 USPQ 161. Applicants are not entitled to procure claims based on discovery that known compositions of matter can be adapted to a new use.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 33 is rejected under 35 U.S.C. 102(b) as being anticipated by Hayashi et al., EP 0 881 218.


Hayashi teaches preventives/ remedies, pharmaceutical compositions and commercial packages comprising 4- α -hydroxy-2-methyl-5-(1-imidazolyl)benzyl]-3,5-dimethylbenzoic acid. See page 4, lines 28-30. Intended use confers no patentable weight to composition claims. In re Hack, 114 USPQ 161. Applicants are not entitled to procure claims based on discovery that known compositions of matter can be adapted to a new use.

No claim is allowed.

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Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

November 26, 2003

A handwritten signature in black ink that reads "Phyllis Spivack". The signature is written in a cursive style with a large, stylized 'P' and 'S'.

**PHYLLIS SPIVACK
PRIMARY EXAMINER**